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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Jamie M. Grooms et al.

: GROUP ART UNIT: 3732 (Anticipated)

SERIAL NO: 09/905,683

: EXAMINER: M. Priddy (Anticipated)

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FOR: CORTICAL BONE CERVICAL
SMITH-ROBINSON FUSION
IMPLANT37 CFR 1.607(a)(4) AMENDMENTASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

✓
Please cancel claims 1-58.

Please add claims 59-110 as follows:

59. A composite bone graft, comprising:

a first cortical bone portion comprising one or more cortical bone planks, and having a

first face comprising protrusions;

a second cortical bone portion comprising one or more cortical bone planks, and having a

second face comprising depressions complimentary to said protrusions provided on said first

face, said second cortical bone portion is provided on said first cortical bone portion such that

said first face and said second face interlock to form a graft unit; and

a cortical bone locking pin located approximately parallel or perpendicular to the

interface of said first cortical bone portion and said second cortical bone portion, said cortical bone locking pin partially traverses said graft unit, wherein said composite bone graft does not comprise an adhesive.

60. A composite bone graft, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

61. A composite bone graft, consisting essentially of:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially

planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

62. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

63. A composite bone graft, consisting essentially of:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions, and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

64. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

65. A composite bone graft, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

66. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone portion to form a graft

unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

67. The composite bone graft of claim 66, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

68. The composite bone graft of claim 67, said first cortical bone portion comprises a first face comprising a [single] protrusion and said second cortical bone portion comprises a second face comprising a [single] depression complimentary to said first face, such that said first face and said second face interlock wherein said composite bone graft does not comprise an adhesive.

69. The composite bone graft of claim 68, said one or more biocompatible mechanical connectors comprise a single cortical bone pin.

70. The composite bone graft of claim 69, said cortical bone pin comprises a locking pin, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion.

71. The composite bone graft of any one of claims 60, 62, 64, 65, or 66, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

72. A composite cervical wedge, comprising:
a first substantially planer cortical bone portion;
a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said

composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a composite anterior height of from about 7 mm-14 mm; a composite posterior height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern, and wherein said composite bone graft does not comprise an adhesive.

73. A composite cervical block, comprising:

a first substantially planar cortical bone portion;

a second substantially planar cortical bone portion provided on said first substantially planar cortical bone portion to form a graft unit said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planar cortical bone portion and said second substantially planar cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a

composite height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern, and wherein said composite bone graft does not comprise an adhesive.

74. The composite bone graft of any one of claims 60, 62, 64-66, 72, or 73, further comprising osteogenic materials provided in said through-hole, said osteogenic materials comprising demineralized bone.

75. The composite bone graft of claim 74, said osteogenic materials further comprising bone morphogenic protein.

76. The composite bone graft of claim 75, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm.

77. The composite bone graft of any one of claims 59, 60, 62, 64-66, 72, or 73, said bone portions comprising allogenic bone.

78. The composite bone graft of claim 65, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone.

79. The composite bone graft of claim 78, said cortical bone and said cancellous bone, comprising allogenic bone.

80. The composite bone graft of claim 65, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm; a width of from about 7 mm-14 mm; an anterior composite height of from about 7 mm-14 mm; and a posterior composite height of from about 7 mm-14 mm.

81. The composite bone graft of claim 80, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

82. The composite bone graft of any one of claims 73 or 81, said plurality of protrusions having a height of about 4 mm.

83. The composite bone graft of any one of claims 60, 61, 66, 72, or 73, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

84. The composite bone graft of any one of claims 62-64 or 65, each of said cortical bone portions comprises one or more cortical bone planks.

85. The composite bone graft of claim 71, said plurality of protrusions having a height of about 4 mm.

86. A composite bone graft, comprising:

a first cortical bone portion comprising one or more cortical bone planks, and having a first face comprising protrusions;

a second cortical bone portion comprising one or more cortical bone planks, and having a

second face comprising depressions complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion, said cortical bone locking pin partially traverses said graft unit.

87. A composite bone graft, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion.

88. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said

adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

89. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions.

90. A composite bone graft, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion.

91. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions .

92. The composite bone graft of claim 91, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

93. The composite bone graft of claim 92, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock wherein said composite bone graft does not comprise an adhesive.

94. The composite bone graft of claim 93, said one or more biocompatible mechanical connectors comprise a single cortical bone pin.

95. The composite bone graft of claim 94, said cortical bone pin comprises a locking pin , said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion.

96. The composite bone graft of any one of claims 87, 88, 89, 90, or 91, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern .

97. A composite cervical wedge, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit, said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit , said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm}; a second width of from about 7 mm-14 mm; a

composite anterior height of from about 7 mm-14 mm; a composite posterior height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern.

98. A composite cervical block, comprising:

a first substantially planar cortical bone portion;

a second substantially planar cortical bone portion provided on said first substantially planar cortical bone portion to form a graft unit, said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planar cortical bone portion and said second substantially planar cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a composite height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured

surface comprises a plurality of protrusions defining a saw-tooth pattern.

99. The composite bone graft of any one of claims 87-91, 97, or 98, further comprising osteoinductive substances provided in said through-hole, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone.

a 100. The composite bone graft of claim 99, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor.

101. The composite bone graft of claim 100, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm.

102. The composite bone graft of any one of claims 86-91, 97, or 98, said bone portions comprising allogenic bone.

103. The composite bone graft of claim 90, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone.

104. The composite bone graft of claim 103, said cortical bone and said cancellous bone, comprising allogenic bone.

105. The composite bone graft of claim 90, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm; a width of from about 7 mm-

14 mm; an anterior composite height of from about 7 mm-14 mm; and a posterior composite height of from about 7 mm-14 mm.

106. The composite bone graft of claim 105, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

107. The composite bone graft of any one of claims 98 or 106, said plurality of protrusions having a height of about 4 mm.

108. The composite bone graft of any one of claims 61, 87, 91, 97, or 98, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

109. The composite bone graft of any one of claims 63, 88, 89, or 90, each of said cortical bone portions comprises one or more cortical bone planks.

110. The composite bone graft of claim 96, said plurality of protrusions having a height of about 4 mm.